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Retrojugular versus Ventrojugular Approach to Carotid Bifurcation for Eversion Endarterectomy: A Prospective Randomized Trial

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Objectives. *The aim of this prospective randomized study was to demonstrate the comparability of retrojugular access for carotid eversion endarterectomy compared to the conventional ventrojugular procedure.*
Patients and methods. *Due to the expected minor and major complication rate of 5% in patients undergoing carotid surgery, a patient cohort of 600 study patients was planned. All patients underwent standard preoperative and postoperative assessment including clinical investigation and fiberoptic laryngoscopy. The 6 month follow-up examination included an evaluation of patient contentment, a duplex scan, clinical investigation and a fiberoptic laryngoscopy.*
Results. *After the first interim evaluation of 101 patients, the study was stopped because of a significant increase in temporary ipsilateral vocal cord motility dysfunction in the retrojugular access group (31% vs. 6%, $p = 0.0014$). This early postoperative impairment was, however, not statistically significant at the follow-up examination at 6 months (2.4% vs. 0%). No other significant differences concerning major complications (death or stroke), other cranial nerve injuries, wound healing, or patient satisfaction was observed neither in the early postoperative phase nor at follow up.*
Conclusion. *Due to the high incidence of temporary ipsilateral vocal cord dysfunction in patients undergoing retrojugular exposure of the carotid artery, we recommend the conventional ventrojugular approach, which can be performed by incision along the anterior border of the sternomastoid muscle or by transversal skin incision.*

Keywords: Carotid surgery; Retrojugular access; Eversion endarterectomy; Cranial nerve injury.

Introduction

Carotid endarterectomy, the standard treatment for severe symptomatic and asymptomatic carotid artery stenosis, is a commonly performed vascular surgical procedure. According to numerous large, randomized and prospective studies the benefit of surgery increases when the incidence of complications decreases.[1,2] Controversial issues, however, still include the type of access, the anesthesia procedure, the way of neuromonitoring, and the use of shunts. In particular, the type of surgical access can determine the extent of cranial nerve damage, which may lead to paraesthesia, dysarthria or dysphagia. The incidence of these complications is not well documented because of the lack of a standardized method for identification and the wide variability reported between retrospective and prospective studies.[3,4] Most studies dealing with this problem present results after standard exposure performed by an incision along the anterior border of the sternomastoid muscle and preparation of the jugular vein laterally (ventrojugular route). In recent years, another access route via transversal skin incision and carotid artery exposure by preparation of the jugular vein medially (retrojugular route) has been described. The cosmetic results of this method seem to be favorable,[5] division of the lymphatic structures or any major branches of the jugular vein can be avoided and high exposure of the internal carotid artery does normally not require mobilization of the hypoglossal nerve.[6] Furthermore a shorter operating time related to the simplicity of the anatomic dissection was observed.[6,7] No published study has described any increase in perioperative strokes or cranial nerve injuries. However, all of these investigations were based on relatively small patient samples and only one study,[7] focused on the anesthetic regime, was based on a prospective randomized design. Therefore we performed a prospective randomized

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study comparing both access methods with respect to surgical feasibility, clamping times, postoperative complications, and patient satisfaction at 6 month follow-up.

Patients and Methods

Study design

The study was planned by the department of vascular and endovascular surgery in collaboration with the department of ear, nose and throat medicine at the University of Regensburg and approved by the local ethics committee of the University of Regensburg (ethical vote No.05/123). The null hypothesis proposed the comparability of both access methods with respect to major complications intra- and postoperatively, cranial nerve injuries as well as patient satisfaction (scale 1 to 10). Only elective patients with symptomatic carotid artery stenosis $>50\%$ or asymptomatic stenosis $>70\%$ (DEGUM criteria[9]) were included. Preoperatively imaging of the brain by CT scan or MRI and of the carotid stenosis either by MRA, CT or angiography was performed in all patients. Exclusion criteria were previous operations or radiation to the same neck site. All study patients were examined clinically using a standardized protocol evaluating the three branches of facial nerve, the accessory nerve and the hypoglossal nerve as well as a standardized fibre-optic laryngoscopy[10] to detect impairment of the vagal/recurrent laryngeal nerve preoperatively, postoperatively on day 2 or 3 and at follow-up after 6 months. Standard technique for surgery was eversion endarterectomy[11] or, if impossible, PTFE interposition ($n=2$). Intraoperative parameters included the subjective overview as rated by the surgeons (1 = easy access to carotid bifurcation, 2 = standard exposure of the carotid bifurcation, 3 = difficult access to the carotid bifurcation), necessity of shunting, and incision to suture and clamping time. In total, 101 patients between September 2005 to March 2006 were enrolled in the study; due to a significant increase in cranial nerve injuries in the retrojugular group, the study was stopped after the first interim evaluation (Fig. 1).

Operative procedures

All operations in the study patients were performed by three experienced vascular surgeons, each of whom had an exposure of more than 100 carotid operations per year. Surgery was performed in supine position either under general ($n=94$) or regional anaesthesia ($n=7$) with the use of heparin (110 IU/kgBW) and aspirin (ASS 100 mg).

Ventrojugular access (VJ)

The ventrojugular approach involved a skin incision at the anterior border of the sternomastoid muscle, dividing of the platysma, exposure and curbing of the common carotid artery by leaving the jugular vein lateral with ligation of crossing vein branches. Subsequent preparation of the bifurcation, internal and external carotid artery and exposure of the hypoglossal nerve was performed. After clamping, the eversion was completed in the conventional manner[11] and subsequently on-table angiography, careful haemostasis, drainage and layered wound closure were performed. (Fig. 2a).

Retrojugular access (RJ)

Skin incision was performed in a transverse neck skin fold. After the platysma was divided, the carotid artery was exposed by preparation of the internal jugular vein ventrally. If necessary, the vagus nerve was taken laterally and after curbing the common carotid artery and bifurcation, the internal and external carotid arteries were exposed. Exposure of the hypoglossal nerve was only rarely necessary in this procedure. After clamping, the eversion was done according to the usual technique followed by on-table angiography, careful haemostasis, drainage and wound closure (Fig. 2b).

In both groups neuromonitoring included the measurement of stump pressure and sensory evoked potentials in all patients. Shunt criteria in patients under general aenesthesia were a stump pressure below 40 mmHg or an decrease in the sensory evoked potentials by more than 70% In patients operated under local anesthesia shunting was either performed in case of contralateral hemiplegia or in case of unconsciousness of the patients.

Statistical methods

Due to the expected complication rate of 5%, a cohort of 600 study patients was required to examine the null hypothesis (Fisher's Exact Test, StatXact-7) and a interim evaluation was planned after 100 and 300 patients.

A permuted blocked randomisation was used in order to have equally sized trial groups at the end of each block. Blocks of four (A;B;C;D) were permuted (A and C meaning retrojugular and B and D meaning ventrojugular approach) and then allocated to a sequence of random numbers. The patients were

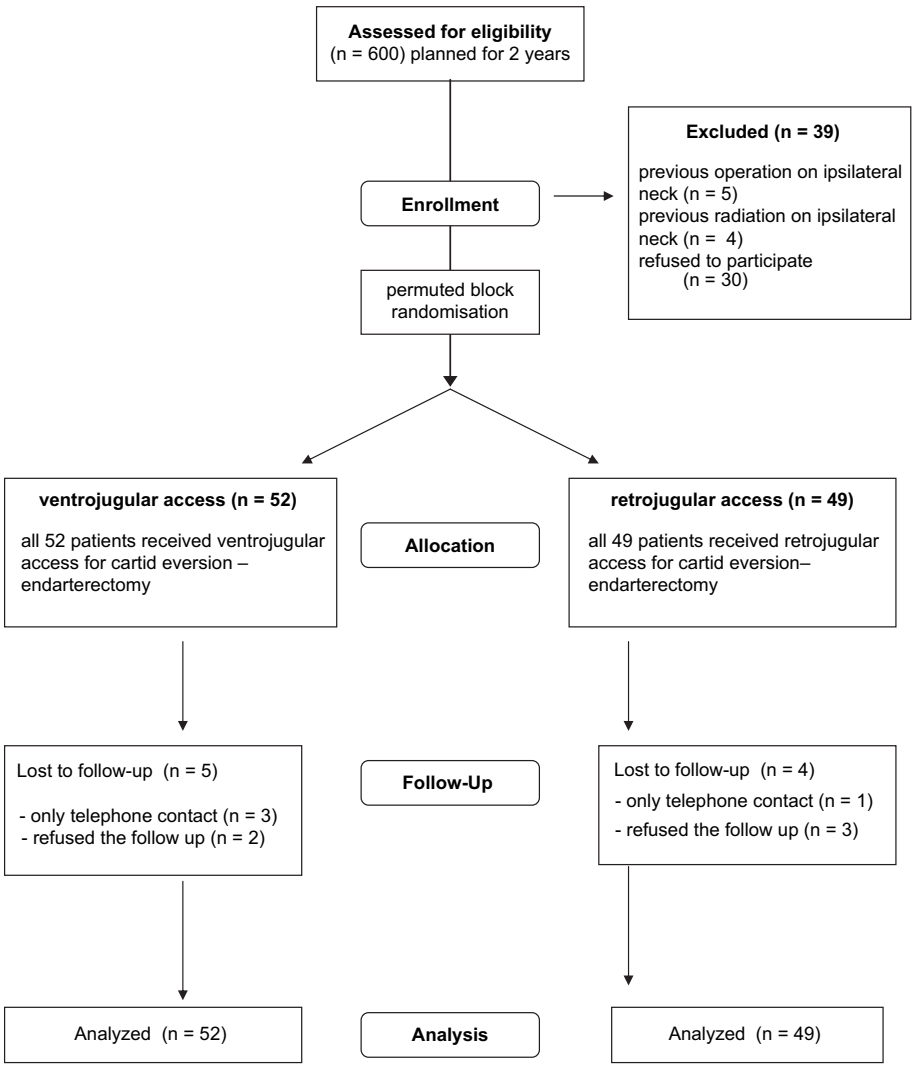

Fig. 1. Flow chart of patients recruitment.

randomised consecutively following the list of appointments. The surgeon as well as the patient were blinded until anaesthesia was given to the patient in the operating room. Opaque envelopes were used to communicate the surgical access route.

To compare qualitative variables Fisher exact test was used. P values < 0.05 were considered significant.

Results

Patients, operative procedure, and hospitalization

49 of the 101 patients were operated on using the retrojugular and 52 using the ventrojugular approach. The retrojugular group (RJ) consisted of 18 women and 31 men, the ventrojugular group (VJ) consisted of 18 women and 34 men. The median age in the retrojugular group was 73 years (min: 42; max: 88), and in the ventrojugular group 70 years (min: 54; max: 84). Risk factors, extent of stenosis or number of ipsilateral intracranial stenoses (tandem stenosis) were not significantly different between the groups (Table 1).

In 99 patients an eversion endarterectomy was performed, and in two patients a reconstruction with a 6 mm PTFE interposition was necessary. Shunting was performed in 5 patients of the ventrojugular group (9.6%) and 11 patients of the retrojugular group (22.4%). This difference was not statistically significant. We did not observe any significant differences in clamping time (VJ mean 27.0 ± 8.7 min vs. RJ mean 27.7 ± 12.6 min), operation time (VJ: mean $65.5 \pm 13{,}2$ min vs. RJ: mean 66.6 ± 19.3 min) or intraoperative overview (VJ: mean $1.1 \pm 0{,}2$ vs. RJ: mean $1.4 \pm 0{,}6$). The median length of postoperative stay

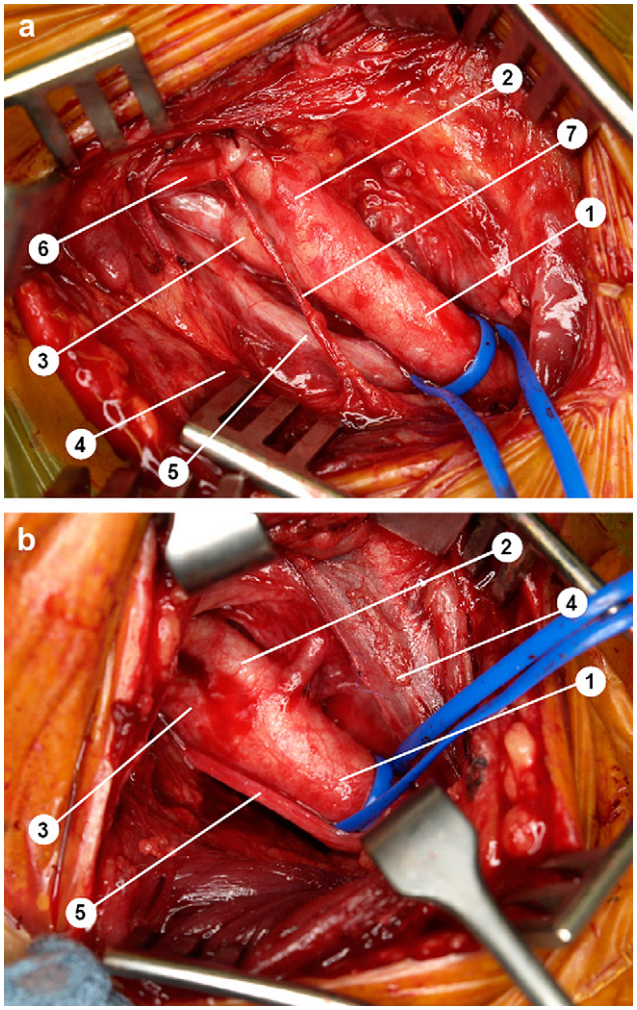

Fig. 2. a. Ventrojugular exposure; 1: common carotid artery, 2: external carotid artery, 3: internal carotid artery, 4: jugular vein, 5: vagus nerve, 6: hypoglossal nerve, 7: ansa cevicalis. b. Retrojugular exposure: 1: common carotid artery, 2: external carotid artery, 3: internal carotid artery, 4: jugular vein, 5: vagus nerve.

in the hospital was 4 days in both groups (VJ: 3 to 33 days vs. RJ: 3 to 22 days).

Death and major stroke

During hospitalization, two study patients died; one in the ventrojugular group and one in the retrojugular group. The patient operated on using the ventrojugular approach died on postoperative day 34 from heart failure after coronary stenting on the first postoperative day. The second patient was operated on with a 6 mm PTFE interposition using the retrojugular approach due to weak adventitia after eversion. This patient died of multiple organ failure on postoperative day 24 as a result of a recurrent postoperative cerebral embolism despite of systemic anticoagulation.

Table 1. Asymptomatic/symptomatic patients, risk factors, extent of stenosis and anesthesia

n	Ventrojugular access *n* = 52		Dorsojugular access *n* = 49		
	n	%	*n*	%	
Asmptomatic stenosis	33	63.5%	33	67.4%	n.s.*
Symptomatic stenosis	19	36.5%	16	32.6%	n.s.*
Diabetes mellitus	16	30.8%	14	28.6%	n.s.*
Coronary heart disease	23	44.2%	30	61.2%	n.s.*
Peripheral vascular occlusive disease	16	30.8%	14	28.6%	n.s.*
Hypercholesterinemia	12	23.1%	15	30.6%	n.s.*
Hypertriglyceridemia	8	15.4%	9	18.4%	n.s.*
Extent of stenosis					
50%–70%	2	3.9%	5	10.2%	n.s.*
70% to 95%	43	82.7%	39	79.6%	n.s.*
>95%	6	11.5%	5	10.2%	n.s.*
Pseudocclusion	1	1.9%	0	0%	n.s.*
Tandemstenosis	3	5.8%	1	2.0%	n.s.*
General anesthesia	48	92.3%	46	93.9%	n.s.*
Regional anesthesia	4	7.7%	3	6.1	n.s.*

* No statistical significant difference of ventrojugular access group vs. dorsojugular access group.

Cranial nerve lesions

As shown in Table 2, there were no significant differences between groups concerning peripheral injury of the hypoglossal, facial or superficial nerves. However, the interim analysis after 101 patients showed a significant difference between the two groups with respect to the laryngoscopically detected disturbances in motility of the ipsilateral vocal cord. Whereas the ipsilateral vocal cord exhibited hypomobility in 5 of the patients and immobility in 10 of the patients of the retrojugular group (30.6%), only 3 patients had immobility of ipsilateral cord in the ventrojugular group (5.9%). 16 of these patients with cord abnormality developed hoarseness. In the retrojugular group 4 of the 11 patients receiving carotid shunting (36.3%) and 11 of 38 patients not requiring carotid shunting (28.9%) developed vocal cord impairment. Because of these findings, the null hypotheses could no longer be proved and the study was discontinued after 101 patients. An interrelation with independent factors like age of patients, comorbidity, anesthesia, symptomatic/asymptomatic stenosis or surgeon was excluded.

Patient satisfaction

At the time of discharge and at the 6 month follow up all study patients were asked to assess their hospital stay as well as surgical and cosmetic results on a scale of 1 to 10 (1 = very content, 10 = very dissatisfied). There was no difference between the two groups; the median value was 3 with a range from 1 to 9 in both study arms.

Table 2. Perioperative nerve injuries

	Ventrojugular		Dorsojugular	
	Postoperative $n = 51$	6 month follow-up $n = 45$	Postoperative $n = 49$	6 month follow-up $n = 41$
N. hypoglossus	1 (2.0%)	0	1 (2.2%)	0
N. facialis	2 (3.9%)	0	1 (2.2%)	0
N. laryngeus recurrens $\boldsymbol{p = 0.0014}$	3 (5.9%)	0	15 (31.3%)[§]	1 (2.4%)
Paraesthesia cervical and ear area	23 (45.1%)	4 (8.9%)	28 (59.6%)	5 (11.1%)

[§] p: Fisher's Exact Test.

Follow-up 6 months

A total of 86 patients (86.7%) (VJ: 45 patients [88%], RJ: 41 patients [85%]) of the 99 discharged patients could be included in the follow-up. 4 patients had died in the meantime for procedure-unrelated reasons, nine additional patients were still alive but did not come to the re-evaluation. Concerning vocal cord motility, only one patient in the retrojugular group showed persisting impairment of the recurrent largyngeal nerve, in all other patients laryngoscopy was normal (Table 2).

Concerning the cranial nerve injuries, the early deficits that had been seen in the hypoglossal and fascial nerves in five patients were no longer detectable, and the paraesthesia of the cervical and ear area had ceased in both groups (VJ 9.1% at 6 months vs. 45.1% postoperatively, RJ 12.2% at 6 months vs. 59.6% postoperatively). We found 4 patients (4.8%) (VJ: 2 patients; RJ: 2 patients) with a mild re-stenosis of the carotid artery (<50%, Ultrasound, DEGUM), currently without any clinical impact. The satisfaction, including the cosmetic result, of the patients at 6 months had improved in both groups as compared with the early postoperative value (VJ: 2.3 ± 2.1 mean vs. 3.1 ± 1.5 mean postoperatively, RJ: 1.9 ± 1.5 mean vs. 3.0 ± 2.3 mean postoperatively). We could not detect any intergroup significance. One patient in each group (VJ: 2.3%, RJ: 2.2%) had developed a keloid scar.

Discussion

This study aimed to demonstrate the value of a retrojugular access as compared to the ventrojugular access in carotid artery surgery. To date, cosmetic advantages, less operation trauma and shorter operation time with no observed higher incidence of minor or major complications, have been described in several studies.[5–8] However, the large number of ipsilateral vocal cord mobility impairment in patients in the retrojugular access group in the early postoperative period led to the interruption of our study after 101 patients. Albeit the vocal cord motility impairment was only temporary and not detectable after 6 month follow up, we did not resume the study because of the disadvantage of temporary hoarseness of many of the patients treated by the retrojugular access without any significant benefit.

While mortality, myocardial infarction, and risk of stroke in patients undergoing carotid surgery is well documented,[1,2] the risk of cranial nerve injuries remains unclear. Several reasons exist, namely the lack of a standardized method for identification, and a wide variability reported between retrospective and prospective studies.[12–14]

Investigations using a conventional ventojugular approach describe an impairment of the branches of the vagus in 1.7% to 7.9% of cases.[3,14] However, published studies comparing both types of access give either no information about the vocal cord motility[6] or have a low incidence of injuries to the recurrent laryngeal nerve.[7,8] Therefore, the result of our interim evaluation was quite alarming, since more than 1/3 of the patients treated by the retrojugular approach showed a disturbance of the ipsilateral vocal cord. The fact, that at follow up after six month only one of the study patients had disturbances of the ipsilateral vocal cord, affirm, that the mechanism of injury is usually traction or compression rather than division.[12–14] Since in our study any relationship to independent factors like surgeon, age of patient, comorbidity or extent of stenosis were excluded, several explanations are possible:

- The vagus nerve lies posterior to the carotid artery and remains usually in the nerve sheath during the ventrojugular procedure. However, in the retrojugular access the vagus nerve appears in a more superficial plane than does the carotid artery and mobilization of the nerve laterally is often necessary. Through this a temporary impairment due to compression or tension of the vagus nerve may be possible.
- In the retrojugular access group shunting was more often necessary, than in the ventrojugular access group. Insertion of a shunt is associated

with more extended dissection and therefore with a greater tissue-trauma. Use of clamps for shunt-fixation may add to this problem. However, the difference between both access groups with respect to shunting was not significant, while the difference with respect to temporary vocal cord motility was significant.

Injuries to the hypogossal nerve with early postoperatively tongue deviation to the ipsilateral side occurred in 2% in the ventrojugular group and 2.1% in the retrojugular group. All these impairments were temporary and were not present at the time of the six month follow-up visit. Other studies describe the risk of injury to this nerve as ranging from 2.3% to 17.5%.[3,14] In these studies, the risk of a temporary deficit of fascial nerve was 1% to 12% and therefore also in good agreement with our results.

Paraesthesia of the cervical and ear area was a common early postoperatively problem in both access groups and concerned about half of the study patients. The extent of hypoaesthesia/dysaesthesia after carotid exposure is well known and documented in the literature. Mauch *et al.*[15] found a loss of cervical nerve sensation following carotid endarterectomy by a skin incision at the anterior border of sternomastoid muscle in all patients. The incidence of hypoaesthesia/dysaesthesia after transverse skin-incision is poorly documented in the literature[6–8] and remains unclear, but in both of our access groups there was no significant difference. In comparison to our results Mauch *et al.*[15] described a high degree of recovery over a period of months as well.

In addition, there was no difference concerning perioperative mortality, myocardial infarction or stroke. One patient in each group died, one from an intraoperative stroke, the other from cardiac failure. Overall, the risk of death or stroke in our series was 2%, which compares well to the generally reported desirable risk of major complications for carotid surgery (death or stroke) of less than 3%.[16]

The intraoperative exposure was slightly, but not significantly better in the ventrojugular group (1.1 vs. 1.4), perhaps as a result of the better exposure of the internal carotid artery in patients with a high bifurcation. However, all operations could be completed via the randomized access, which is in accordance with other published series.[6–8]

In summary, we observed a significantly higher rate of temporary ipsilateral vocal cord dysfunction in patients undergoing a retrojugular access to the carotid artery, which resulted in early interruption of the study and in abandonment of this type of access in our center. The ventrojugular access appears to be the superior approach to carotid bifurcation.

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